

## REMARKS

The Applicant believes that the following comments will convince the Examiner that the rejections in the April 27, 2006, Final Office Action should be reconsidered and withdrawn.

### I. The Invention

The present invention pertains to a mass spectrometer system in which an empirical formula of an unknown drug compound is identified based on measurements taken during multiple stages. More specifically, fragmentation of the sample ions is further disclosed to obtain results of empirical formulas for biological samples containing one or more unknown drugs.

### II. The Examiner's Rejections

The Examiner rejected claims 30-33 under 35 U.S.C. § 102 (e) as being anticipated by Dasseux et al. US 2002/0019023 ("Dasseux"). According to the Examiner, Dasseux discloses "a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample with metabolic products," "introducing said ions to the analysis region of a mass spectrometer," "continuously monitoring the ion sand detecting changes to the sample," and "determining the molecular weight of each species present in a sample to determine the empirical formula and identifying each species by comparing the empirical formula to a database of formulas." The Examiner rejected claim 31 because in his opinion Dasseux "teach[es] updating databases with the changes that are detected." The Examiner rejected claim 32, arguing that Dasseux teaches that "the mass spectrometer is a FTMS." Finally, the Examiner rejected claim 33 because Dasseux

discloses, “using electrospray ionization as well as chemical,” and “both of these methods are forms of Atmospheric Pressure Ionization.”

### **III. The Examiner’s Rejections Should Be Reconsidered and Withdrawn**

The Examiner rejected claims 30-33 under 35 U.S.C. § 102(e) as being anticipated by Dasseux. Specifically, the Examiner argues that Dasseux discloses the use of molecular peaks to determine the empirical formula of one or more compounds. Applicant respectfully disagrees.

Briefly, Dasseux does not teach using the molecular weight to determine the empirical formula for large molecules such as nucleic acids and/or proteins. Rather, Dasseux teaches that the determination of large molecules requires one or more preliminary steps not needed in the present invention. More specifically, Dasseux teaches that a large molecule of interest must first be pre-fragmented into nucleotides (for nucleic acids) or amino acids (for proteins) by treatment of an enzyme (i.e., the “biochemical approach”). The pre-treated fragments are then introduced into a sample and analyzed using a mass spectrometer, where the fragment peaks are identified. The resulting intensity of the fragment ion peaks is collected and analyzed in a database to determine the specific number and sequence of the respective amino acid/nucleotide, which allows a user to determine the conformational structure of the large molecule.

In contrast, the present invention teaches a method to identify unknown drugs, many of which are large molecules. Because the present invention is directed to determining the structure of unknown products, the present invention does not require a

pre-digestion step of a known large molecule. Indeed, if the user of the present invention already was aware of the drug in the sample, there would be no need to analyze it! In short, Dasseux does not teach this novel aspect of the present invention.

In addition, Dasseux teaches that databases related to unknown drug products currently do not exist. Indeed, the Examiner admits that Dasseux does not disclose such a database: “Dasseux et al. are stating that the databases must be compiled before the peaks can be identified.” In short, Dasseux theorizes the existence of a future system which would require extensive hardware and software applications in order to function properly. It does not disclose, however, the system. Indeed, Dasseux and the Examiner acknowledge that such a database does not exist. Accordingly, Dasseux teaches away from the step of identifying a fragment species in a database as required by independent Claim 30. As such, the Examiner’s rejection is improper and should be withdrawn.

In view of the foregoing, the applicant respectfully requests that this rejection be withdrawn.

Conclusion

Applicant respectfully submits that the present invention as claimed in claims 30-33 represents a patentable contribution to the art and the application is in condition for allowance. Early and favorable action is accordingly solicited.

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Respectfully submitted,



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